



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.10.1999
COM(1999) 544 final

99/0219 (CNS)

Proposal for a

COUNCIL DECISION

**concerning the placing on the market and administration of bovine somatotrophin
(BST) and repealing Council Decision 90/218/EEC**

(presented by the Commission)

EXPLANATORY MEMORANDUM

Council Decision 90/218/EEC concerning the placing on the market and administration of Bovine somatotrophin (BST), was as last amended by Council Decision 94/936/EC extending the moratorium on the marketing and use of BST in the Community until 31 December 1999.

Article 2 of Council Decision 94/936/EC provides that the Commission had to entrust a working Party of independent scientists with the task of assessing the effects of using BST, taking into account of the opinion of the Committee for Veterinary Medicinal Products, in particular as regards the impact of the use of this product on the incidence of mastitis.

The Scientific Committee on Animal Health and Animal Welfare (SCAHAW) adopted on 10 March 1999 its report on Animal Welfare Aspects of the Use of Bovine Somatotrophin and stated that BST increases the risk of clinical mastitis as well as the duration of treatment of mastitis, that it increases the incidence of foot and leg disorders and that it can affect adversely reproduction as well as induce severe reactions at the injection site.

Council Directive 98/58/EC¹ concerning the protection of animals kept for farming purposes states in Annex point 18 that no other substance with exception of those given for therapeutic or prophylactic purposes shall be administered to an animal unless it has been demonstrated by scientific studies of animal welfare or established experience that the effect of the substance is not detrimental to the health or welfare of the animal. BST is not used in cattle for therapeutic purposes, but only to enhance milk production. Therefore it results from the opinion of the SCAHAW that BST should not be used in dairy cows.

The Protocol on protection and welfare of animals annexed to the Treaty of the European Community calls on the Community and the Member States, when formulating and implementing the Community's agricultural policy, to pay full regard to the health and welfare requirements of animals. By Decision 78/923/EEC,² the Community has approved the European Convention for the Protection of Animals Kept for Farming Purposes (hereinafter called 'the Convention') and has deposited its instrument of approval. All Member States have also ratified this Convention.

In the light of this opinion, it is proposed to ban for reasons of animal health and welfare the marketing and use of BST in the Community as from 1 January 2000, in accordance with the provisions laid down in Council Decision 98/58/EC on the protection of animals kept for farming purposes.

This proposal has no impact on imports of dairy products from third countries.

This proposal has no financial bearings on the Community budget.

¹ OJ L 221, 8.8.1998, p. 23.

² OJ L 323, 17.11.1978, p. 12.

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concerning the placing on the market and administration of bovine somatotrophin (BST) and repealing Council Decision 90/218/EEC

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas:

- (1) Council Decision 90 /218/EEC³ concerning the placing on the market and administration of bovine somatotrophin (BST), as last amended by Council Decision 94/936/EC⁴, provides in article 1 that Member States shall ensure that, until 31 December 1999, the placing on the market of bovine somatotrophin for the purposes of its marketing and the administration thereof on their territory to dairy cows by any means whatsoever will not be authorised;
- (2) by virtue of Article 2(2) of this Decision , the Council instructed the Commission to entrust a Working Party of independent scientists, in collaboration with Member States, with the task of assessing the effects of using BST, taking account of the opinion of the Committee for Veterinary Medicinal Products, in particular as regards the impact of the use of this product on the incidence of mastitis;
- (3) Article 2 (1) of this Decision allowed the Member States to carry out limited practical tests on the use of bovine somatotrophin, under the control of an official veterinarian, in order to obtain any other scientific data that may be taken into account by the Council when it takes a final decision. The Commission has not received any information on such tests and in view of the prohibition laid down in this Decision there is no need to continue authorising further such tests;

³ OJ L 116, 8.5.1990, p. 27.

⁴ OJ L 366, 31.12.1994 p. 19.

- (4) the Protocol on protection and welfare of animals annexed to the Treaty of the European Community calls on the Community and the Member States, when formulating and implementing the Community's agricultural policy, to pay full regard to the health and welfare requirements of animals;
- (5) by Decision 78/923/EEC,⁵ the Community has approved the European Convention for the Protection of Animals Kept for Farming Purposes (hereinafter called 'the Convention') and has deposited its instrument of approval. All Member States have also ratified this Convention;
- (6) Council Directive 98/58/EC⁶ concerning the protection of animals kept for farming purposes states in Annex point 18 that no other substance, with exception of those given for therapeutic or prophylactic purposes, shall be administered to an animal unless it has been demonstrated by scientific studies of animal welfare or established experience that the effect of the substance is not detrimental to the health or welfare of the animal;
- (7) the Scientific Committee on Animal Health and Animal Welfare (SCAWAH) adopted on 10 March 1999 its report on Animal Welfare Aspects of the Use of Bovine Somatotrophin and stated that BST increases the risk of clinical mastitis as well as the duration of treatment of mastitis, that it increases the incidence of foot and leg disorders and that it can affect adversely reproduction as well as induce severe reactions at the injection site;
- (8) it is important for the health and productivity of dairy cattle that they are subjected to minimum stress which may lead to increase in diseases such as mastitis, foot lesions and reactions to injection site. It results from the opinion of the SCAWAH that the use of BST has been shown to lead to increases in these conditions, which are both painful and debilitating, and which can lead *inter alia* to loss of productivity, premature culling and death, as well as to poorer welfare. Furthermore, because of their inherently infectious nature, these conditions may spread to other cattle and cause a deterioration in the overall health of the herd.. Therefore it results from the opinion of the SCAHAW that BST should not be used in dairy cows.
- (9) BST is not made to be used in cattle for therapeutic purposes, but only to enhance milk production;

HAS ADOPTED THIS DECISION:

Article 1

As of the entry into force of this Decision, Member States shall ensure that the placing on the market of bovine somatotrophin on their territory or within their jurisdiction for the purpose of its marketing and administration thereof to dairy cows by any means whatsoever shall be prohibited.

⁵ OJ L 323, 17.11.1978, p. 12.

⁶ OJ L 221, 8.8.1998, p. 23.

Article 2

Undertakings buying or producing bovine somatotrophin substances and undertakings authorized in any capacity to market such substances shall be required to keep registers detailing, in chronological order, quantities produced or acquired and those sold or used and the names of the persons to whom such quantities were sold or from whom they were purchased. The above information must be made available to the competent authority at its request and, in the case of computerized records, in the form of a printout.

Article 3

This Decision shall not affect the production of bovine somatotrophin in the Member States, or imports, for the purposes of its export to third countries.

Article 4

Decision 90/218/EEC is repealed as of the entry into force of this Decision.

Article 5

This Decision shall enter into force on 1 January 2000.

Article 6

This Decision is addressed to the Member States.

Done at Brussels,

*For the Council
The President*